

Remarks

Applicant respectfully requests reconsideration. Claims 1, 7-11, 14, 15, 17-21, 24, 34, 43, 56 and 78-104 were previously pending in this application. By this Amendment, Applicant has canceled claim 10 without prejudice or disclaimer. As a result, claims 1, 7-9, 11, 14, 15, 17-21, 24, 34, 43, 56 and 78-104 are pending for examination with claims 1, 24, 34, 43, and 56 being independent claims. No new matter has been added.

Telephone Interview

Applicant's representative wishes to thank the Examiner for the courtesy of a telephone interview conducted on January 30, 2006. During the interview, Applicant's representative and the Examiner discussed reasons why the 103 rejections should be withdrawn. The Examiner indicated the unexpected results and teaching away in respect of the Wooldridge reference, as discussed during the interview, amounted to a good argument. The Examiner requested the argument be presented in writing. In addition, the Examiner indicated during the interview that claims 10 and 11, drawn in pertinent part to C2B8 and Rituximab, respectively, appear to be drawn to identical subject matter.

Objection to Specification

The Examiner objected to the specification for use of the alleged trademark RITUXIMAB. Applicant respectfully submits that Rituximab is a generic name and not a trademark. Accordingly the Applicant has not amended the specification as suggested by the Examiner, and Applicant respectfully requests the Examiner to withdraw the objection to the specification.

Rejections Under 35 U.S.C. §112, First Paragraph

The Examiner rejected claim 100 under 35 U.S.C. §112, first paragraph, for alleged failure to comply with the written description requirement. More particularly, on page 29 of the Office Action the Examiner asserts that he cannot identify where support for claim 100, which

specifies in part that the surface antigen is not expressed on the malignant B cells, can be found in the specification. Literal support for claim 100 can be found, for example, in claim 34 as originally filed, as well as on page 3, lines 11-18 of the specification.. Claim 34 as originally filed reads as follows:

34. *A method for treating lymphoma, comprising:
isolating a B cell from a subject having lymphoma,
identifying a surface antigen which is not expressed or which is expressed
on the surface of the B cell in an amount lower than that of a control B cell,
administering to the subject an antibody specific for the identified surface
antigen and an immunostimulatory nucleic acid in order to treat the cancer,
wherein the immunostimulatory nucleic acid is administered in an effective
amount to upregulate expression of the surface antigen on the cancer cell surface.
[Emphasis added.]*

As can be readily appreciated from the foregoing, claim 34 as originally filed specifically included the limitation that the surface antigen is not expressed. Since a surface antigen is an antigen expressed on a cell and the cell of original claim 34 is a B cell isolated from a subject having a lymphoma, it is respectfully submitted that claim 34 as originally filed provides adequate written description for “surface antigen ... not expressed on the malignant B cells” in claim 100.

Accordingly, withdrawal of the rejection of claim 100 under 35 U.S.C. §112, first paragraph, is respectfully requested.

At the top of page 30 of the Office Action the Examiner went on to assert that to the extent that the claimed compositions and/or methods are not described in the instant disclosure, claim 1 is also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described. It is respectfully submitted that the Examiner intended to direct this rejection toward claim 100, rather than to claim 1. In view of the foregoing with respect to the written description for claim

100, Applicant respectfully submits that this rejection (as apparently intended to be applied to claim 100) is also overcome, since it is expressly delimited by the Examiner "[t]o the extent that the claimed compositions and/or methods are not described in the instant disclosure ...".

Accordingly, withdrawal of this rejection of claim 100 under 35 U.S.C. §112, first paragraph, is also respectfully requested.

Rejections Under 35 U.S.C. §112, Second Paragraph

The Examiner rejected claims 11 and 85 under 35 U.S.C. §112, second paragraph, for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. More particularly, on page 30 of the Office Action, the Examiner asserts that the scope of claims 11 and 85 is uncertain since the claims contain the trademark/trade name RITUXIMAB and a trademark or trade name cannot be used properly to identify any particular material or product. In response, Applicant respectfully points out that Rituximab is a generic name, not a trademark or trade name, for a particular antibody. Thus the rejection is not applicable as Rituximab is neither a trademark nor a trade name.

Accordingly, withdrawal of this rejection of claims 11 and 85 under 35 U.S.C. §112, second paragraph, is respectfully requested.

Rejections Under 35 U.S.C. §103

The Examiner rejected claims 1, 7-11, 14, 15, 17-21, 24, 34, 43, 56, 78-99, and 102-104 under 35 U.S.C. §103(a) as being unpatentable over Wooldridge et al. (*Blood* 89:2994-8 (1997)) in view of various additional references already made of record. Arguments set forth during the telephone interview on January 30, 2006, are restated below.

It will be appreciated that all the claim rejections made under 35 U.S.C. §103(a) depend in part on Wooldridge et al. It will also be appreciated that all claims rejected under 35 U.S.C. §103(a) include, *inter alia*, the limitations that (a) the cells upregulate expression of an antigen in

response to immunostimulatory CpG oligonucleotide and (b) the subject is administered an antibody specific for the upregulated antigen.

Applicant respectfully submits that the claimed feature of upregulation of antigen by CpG is neither taught nor suggested by Wooldridge et al. In fact, Wooldridge et al. specifically teaches away from this particular claimed feature because Wooldridge et al. disclose on page 2997 that CpG had no detected effect on the target cells in the model they studied. Wooldridge et al. teaches instead that immune effector cells, rather than target cells, are affected by CpG oligonucleotide in the particular model they studied. Furthermore, none of the additional references cited in combination with Wooldridge et al. teach or suggest the claimed feature of upregulation of antigen by CpG oligonucleotide. The combination of Wooldridge et al. with any one or more of the additional references cited by the Examiner thus cannot render obvious the claimed subject matter of claims 1, 7-11, 14, 15, 17-21, 24, 34, 43, 56, 78-99, and 102-104 because no combination of references includes the claimed feature that the cells upregulate expression of an antigen in response to immunostimulatory CpG oligonucleotide.

It is respectfully submitted that the enhanced antibody-dependent cellular cytotoxicity (ADCC) reported by Wooldridge et al. relies on ample baseline expression of pertinent antigen by target cells, independent of CpG. Had the target cells (unlike the 38C13 cells of Wooldridge et al.) expressed little or no antigen relevant to the antibody selected for use, and the cells did not upregulate antigen in response to CpG (as Wooldridge teaches they do not), then the skilled person reading Wooldridge et al. would not have expected immune effector cells to exhibit enhanced ADCC even with CpG oligonucleotide present because there would not be sufficient target antigen to support ADCC.

The claimed invention is surprising in view of Wooldridge et al., alone or in combination with any of the references cited by the Examiner, because it was previously unknown that CpG can upregulate expression of certain antigens in malignant B cells. Unlike expression by 38C13 cells of antigen recognized by the antibody in Wooldridge et al., expression of certain antigens by malignant B cells is typically low or absent and can be upregulated in the presence of CpG

oligonucleotide. It would not have been obvious to a person skilled in the art at the time the invention was made to select and use particular antibodies for use in treating B cell malignancies, when the cells of such malignancies express little or no antigen relevant to the particular antibodies, because it was previously unrecognized that CpG can upregulate expression of such antigen by malignant B cells.

Accordingly, withdrawal of this rejection of claims 1, 7-11, 14, 15, 17-21, 24, 34, 43, 56, 78-99, and 102-104 under 35 U.S.C. §103(a) is respectfully requested.


Conclusion

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,
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